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MULTIPLE ANALYTE ASSAY DEVICE**FIELD OF THE INVENTION**

5 The present invention relates to methods and devices for assaying biological fluid samples. More particularly, the invention relates to methods and devices for detecting analytes, such as drugs, in urine.

HISTORY OF THE RELATED ART

In their most simple form, chromatographic analyte test strips permit an assay to be 10 performed in a single step (application of an analyte sample to the device) to produce visually observable assay results (such as those indicated by colored bars on the test strip). However, a common limitation of such test strips is that they can only be used to detect a single analyte, requiring that serial assay procedures be performed to detect additional analytes (for example, to test a sample for the presence of a panel of 15 narcotics). Multiple dipping steps, such as are commonly used when multiple dipstick assays are separately performed, present not only a possible loss of sensitivity of the assay (through reagent mixing or loss of reagent solutions), but also an esthetic and hygienic problem for the analyst. Repetitive performance of assay procedures is also tedious, which increases the risk that assays will be performed improperly or the results 20 misinterpreted.

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SUMMARY OF THE INVENTION

The present invention provides an assay device, device for separating a fluid analyte sample for use in multiple assay procedures and methods for performing multiple analyte assays. In one embodiment of the assay device, the assay device is a dipstick having 5 multiple analyte test strips, each of which includes a test zone and a control zone. The test strips are enclosed in a housing having an open side through which an end of each test strip protrudes to form a sample loading zone. A protective cap is provided to seal the protruding ends of the test strips from exposure while not in use. Each test strip is separated from the next within the housing by a raised spacer. The portion of the housing 10 which overlies the test and control zones is transparent to permit visually observable results shown in each zone to be viewed.

In cassette form, the assay device has the same structure described above, but the protruding test strips are inserted into a cap which has a sample port for application of sample to the test strips. The cap is retained on the assay device by a close fit over the 15 device housing.

Each test strip provides binders and assay reagents for detection of a different analyte in the sample fluid. In a particularly preferred embodiment of the assay device, the housing may be opened to permit substitution of different test strips to allow each device to be customized for detection of specific analytes of interest. Assay sample integrity 20 determinants consisting of test strips which allow measurement of parameters such as specific gravity and pH may also be included in each device.

The invention also provides a separator device for dividing a fluid assay sample into portions for use in multiple assays without need for contact between the assay operator and the fluid sample. This latter feature of the device increases operator safety and 25 avoids inadvertent contamination of the assay sample. The separator device may be used to separate any fluid assay sample, but is especially useful in assaying samples for the

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presence of narcotics, where a positive result on first testing of the sample may necessarily be followed by additional testing of the sample to confirm the result and the identity of the detected narcotic. To this end, the separator device is adapted particularly well to use with the assay device of this invention.

- 5 The assay device of the invention makes specimen analysis easier because an analyte sample need only to be applied once to the assay device for testing. In addition, the replaceable nature of the analyte test strips allows the analyst to customize the array of assays to the testing situation. Because the customization can be performed before adding the test sample (e.g., urine), fewer manipulations with the analyte sample are needed to
- 10 obtain the desired information. In addition, use of the separator device permits further testing of the sample to be performed without risk of adulterating the sample in a preliminary assay performed according to the invention.

The invention also provides a method for assaying one or more analytes of interest. The protruding ends of the device are dipped into a fluid analyte sample. Binding of an analyte present in the sample with one or more specific ligands causes formation of specific visual pattern in the test and control zones indicative of the test result. The assay results performed according to the invention may be read visually without use of separate measuring equipment. Thus, performance of assays according to the invention requires only that the user introduce the requisite amount of test sample into the device of the invention, then observe any color changes which appear shortly thereafter in a detection zone of an analyte strip. The method of the invention is especially useful for screening fluid analyte samples (e.g., urine) for the presence or absence of drugs of abuse.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an exploded view of a dipstick assay device of the invention.

FIGURE 2 is a top view of a dipstick assay device of the invention.

FIGURE 3A is a top view of the upper half sample port cap of a cassette assay device of
5 the invention, and FIGURE 3B is a top view of the lower half, base portion of the sample
port cap, while FIGURE 3C is a side, cut-away view of the intact cap with test strips in
place therein.

FIGURE 4 is a top view of the separator device of the invention.

FIGURE 5 is a cross-sectional view of the separator device taken along line A-A at cut-
10 away point B-B of FIGURE 1.

FIGURE 6 is a lateral view of the separator device within a specimen collection cup.

Like numerals refer to like elements in the drawings.

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DETAILED DESCRIPTION OF INVENTION

A. Definitions

For ease of understanding, the following definitions will apply throughout this description:

5 1. The term "antigen" as used herein refers to any analyte which is capable of binding antibodies. Antigens may comprise, without limitation, chemical compounds, polypeptides, carbohydrates, nucleic acids, lipids, and the like, including viral particles, viral subunits, bacterial and parasite surface antigens, and host proteins that may be diagnostic of the subject's condition.

10 2. A "binder" refers to a ligand for the analyte as in the format of a sandwich assay, or a ligand for both the analyte and the tracer as in the format of a competitive assay. A binder can be chosen from a group of molecules or compounds capable of binding the analyte, such as an antigen to the antibody analyte, or an antibody to the antigen analyte.

15 3. A "test zone" refers to an area in which a binder or the analyte is attached, movably or immovably, to the test strip portion of an assay device.

4. A "tracer" refers to a ligand for the analyte or the binder labeled with a detectable label, preferably a visually readable particulate label, such as colloidal gold, latex and liposomes including dye, carbon black, and the like.

20 5. A "sample loading zone" refers to an area of a test strip on which a fluid analyte sample is applied for migration to the test zone.

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6. A "test strip" of the invention consists of, collectively, all of the zone supporting membranes and any filters of the assay device.

7. A "fluid analyte sample" can be any fluid suspected of containing analyte of interest for which a particular assay is specific. Test sample may represent any 5 body fluid, including urine, blood, sweat, lymph, intraperitoneal fluid, crude tissue extract or homogenate, derived from a fetus, neonate, juvenile or adult subject; a non-biological fluid such as water from some ecological niche, e.g., a river or a lake; or a solution used in a laboratory.

8. A "label" is a molecule or compound which directly or indirectly 10 mediates the formation of a signal (such as a color change) which is used in assay to indicate the presence, absence or concentration range of analyte of interest in a test sample. Labels may include enzymes, fluorescers, liposomes, erythrocyte ghosts, polymer microcapsules, color polymer particles (latex), and preferably includes sols of metal-containing compounds. A wide variety of patents and patent applications provide 15 an extensive literature of different techniques for producing detectable signals in immunoassays. The following list of United States patents is merely illustrative of the type of label which can find application in this invention: U.S. Patent Nos. 3,646,346 discloses radioactive label; 3,654,090, 3,791,932, and 3,817,838 disclose enzyme labels; 3,996,345 discloses fluorescer-quencher labels; 4,062,733 discloses radioactive label; 20 4,067,959 discloses fluorescer or enzyme label; 4,104,099 discloses chemiluminescent label; and 4,160,645 discloses non-enzymatic catalyst label. U.S. Patent No. 3,966,879 discloses an electrophoretic technique employing an antibody zone and U.S. Patent No. 4,120,945 discloses a radioimmune assay (RIA) where labeled analyte is initially bound 25 to a solid support through antibody. U.S. Patent No. 4,233,402 discloses enzyme pair labels; U.S. Patent No. 4,720,450 discloses chemically induced fluorescent labels; and U.S. Patent No. 4,287,300 discloses enzyme anionic charge labels.

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Labels can also be metal-containing sols; *i.e.*, metal or metal compounds such as metal oxides, metal hydroxides, metal salts, metals or metal-containing compounds mixed with polymers or coated onto polymer nuclei. These metal labels may include dry forms of any of the above-named metal or metal compound sols, and preferably includes

5 colloidal gold in dry form.

9. A "complex" means (depending on the context) any multimolecular complex formed by analyte and one or more ligands, or by labeled ligand and immobilized ligand. In a sandwich-type immunoassay, *e.g.*, the following complexes

10 occur: analyte/labeled ligand duplex first produced in the assay (first complex) and analyte/labeled ligand/immobilized ligand triplex formed second in the assay (second complex).

10. "Fluid communication" refers to structures which are in contact with,

15 but not necessarily affixed to, one another.

11. "Assay" refers to several different types of assay formats in which an analyte of interest can be detected using an assay test strip. For example, in a sandwich-type immunoassay, analytes of interest in the analyte sample, when present, bind a labeled tracer movably incorporated in the test strip (consisting of a porous membrane)

20 at the tracer zone to form a first complex. The tracer is a molecule which binds the analyte of interest and is conjugated to a label, preferably a metal label, and most preferably colloidal gold.

A second immobilized ligand corresponding to the analyte of interest is coupled to the test strip at the test zone. First complex and unbound labeled ligand mix

25 with the test sample and be carried along therewith by capillary action (wicking) through the test zone. Analyte sample passes through the test strip bringing the first complexes, if any, into contact with the unlabeled ligand immobilized in the test zone to form a second complex of labeled ligand-analyte-immobilized ligand. The first immobilized

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A second immobilized ligand corresponding to the analyte of interest is coupled to the test strip at the test zone. First complex and unbound labeled ligand mix 25 with the test sample and be carried along therewith by capillary action (wicking) through the test zone. Analyte sample passes through the test strip bringing the first complexes, if any, into contact with the unlabeled ligand immobilized in the test zone to form a second complex of labeled ligand-analyte-immobilized ligand. The first immobilized

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ligand is immobilized in the test zone by means known in the art, including covalent bonding or attachment to an insoluble protein-coated surface (see, e.g., U.S. Patents No. 4,200,690 and 5,075,078). When the second complex is formed, a visible color pattern appears in the test zone. Labeled ligand not bound to analyte in the test sample continue 5 migration by wicking into the control zone to contact the ligand immobilized there. The labeled ligand can bind the immobilized ligand in the control zone to form a third complex, and thus be captured in the control zone.

Within the scope of this invention, the labeled ligand forming the complex in the control zone may be the same as the tracer forming the first and second complexes, 10 or it may be a different labeled ligand. The ligand immobilized in the control zone should have specific affinity for the labeled ligand intended to form the third complex. Formation of the third complex is indicated by a visible pattern in the control zone.

Besides sandwich immunoassay method, other assay methods may be implemented in the devices of the invention. These methods may include competition 15 and inhibition assays. In a competition assay, the analyte and tracer have similar affinity properties and compete for binding with immobilized ligand. Thus, in absence of analyte, the pattern (e.g., band) in the test zone is of maximum intensity. When present, the analyte binds to immobilized ligand to prevent the tracer from getting captured in the test zone. Thus, the intensity of the test band is reduced, depending on the concentration of 20 analyte in the test sample.

In an inhibition assay, the analyte and immobilized ligand in the test zone each have affinity for the tracer. In the absence of analyte in the analyte sample, the tracer is captured by immobilized ligand, and a visible pattern forms in the test zone. When present, the analyte binds the tracer, thereby preventing it from binding to the 25 immobilized ligand in the test zone. The resulting intensity of the test band is reduced depending on the concentration of analyte in the test sample.

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B. Dipstick Assay Device

Turning to FIG. 1, a dipstick form of the assay device is shown in exploded view. The device consists of a housing 100, which is defined by base 101 and cover 110. Base 101 can be constructed of any sterilizable material, such as a nonporous plastic (e.g., the 5 commercially available plastic "ABS" supplied by the Monsanto Company of St. Louis, MO.). Base 101 having a closed end 104 and an open end 106, slots 102A, 102B, 102C, 102D and 102E separated by rails 103A, 103B, 103C and 103D for insertion of test strips 105A, 105B, 105C, 105D and 105E. A particular advantage of this embodiment of the assay device is its customizability in that test strips specific for different analytes of 10 interest to the user may be inserted into base 101 and that the number of test strips employed may vary (e.g., base 101 may have any number of slots from two upward to accomodate as many test strips as the user may desire).

Referring to FIG. 2, when inserted into slots 102A, 102B, 102C, 102D and 102E, the test strips extend out of base 101 beyond open end 106. The length to which the test strips 15 protrude from base 101 must be sufficient to allow the test strips to contact a fluid analyte sample, preferably by immersion, and most preferably without allowing the fluid to contact housing 100. The test strips are conventional in form; therefore, because those of ordinary skill in the art will be abundantly familiar with the design of such test strips, they will not be described in detail here. However, each test strip will have a test zone 20 112 for binding of analyte (to indicate a positive test result for the presence of analyte in the analyte sample) and a control zone 113 for binding of tracer (to indicate correct operation of the assay). Preferably, the test zones and control zones of each test strip lie in the same location on each test strip so each can be viewed in side-by-side fashion.

Each test strip is typically constructed of a porous membrane which is substantially inert 25 with respect to the analyte and must be porous or absorbent relative to the analyte sample to be tested, e.g., urine. The substance can be either bibulous matrices or nonbibulous matrices that are insoluble in, and maintain their structural integrity when exposed to

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and US Patent No. 5,602,040, the disclosures of which are incorporated for purposes of reference.

Test strips 105A, 105B, 105C, 105D and 105E may be secured within slots 102A, 102B, 102C, 102D and 102E by adhesion to the floor of each slot; however, the placement of

5 cover 110 onto base 101 is sufficient to retain the test strips within the base slots. To this end, cover 110 is conveniently constructed of an opaque tape having at least one transparent window 111 formed therein for viewing of test results along test zone 112 and control zone 113. To secure cover 110 onto base 101, as well as to secure test strips 105A, 105B, 105C, 105D and 105E within slots 102A, 102B, 102C, 102D and 102E,

10 cover 110 is pressed into place to form an adhesive attachment between cover 110 and the upper edges of rails 103A, 103B, 103C, and 103D. To provide additional surface area for adhesion of cover 110 to base 101, bar 107 separates closed end wall 104 of base 101 from rails 103A, 103B, 103C, and 103D.

15 Conveniently, cover 110 is also provided with transparent windows 115A, 115B, 115C, 115D and 115E through which labels on test strips 102A, 102B, 102C, 102D and 102E can be viewed. The labels (not shown) may be printed with information of use in performing the assay, such as the identity of analyte detectible with each test strip.

In certain instances, it may be desirable to store the assay device after test results are

20 obtained for later viewing. To that end, a five-sided cap 120 is provided for insertion over open end 106 of base 101 (with cover 110 in place) to protect the protruding ends of test strips 102A, 102B, 102C, 102D and 102E from contact with other materials, from dessication and from contact with the assay operator. Cap 120 is easily secured onto the assay device by a close fit, such as a friction fit or snap-fit.

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collection chamber is lower than the level of the assay device housing. The uncontaminated balance of the assay sample still in the specimen collection cup is available for further testing; e.g., for mass spectrometry to determine the identity of any compounds detected in the initial assay of the portion of the sample separated in the 5 separator device. Conveniently, the separator device may be provided in the form of a kit, including the separator device, a sterilized specimen collection cup with cap and forceps for removal of the separator device from the cup after performance of the assay. Such a kit may also be provided with the assay device of the invention.

An example of a separator device is shown in Figures 4 through 6. Although the 10 separator device shown is in the shape of a ring (to correspond to the common cup-like shape of urine collection cups), those of ordinary skill in the art will recognize that the separator device may be of any shape which conforms to a specimen collection container having at least one open end into which the separator device may be seated.

Referring to FIG. 4, a top view of separator device 400 is provided. Ring 401 has an OD 15 of slightly less than the ID of the specimen collection cup into which the separator device is to be placed. Collection chamber 402 spans ring 401 and is defined by walls 403 and 404.

Looking through separator device 400 along line A-A from cut-away point B-B (FIG. 5), it is seen that walls 403 and 404 meet at point 405 to form a V-shaped well. Those of 20 ordinary skill in the art will recognize that collection chamber 402 may take the form of a half-circular, squared or other shaped well, but a V-shape is a convenient well form to manufacture. Collection chamber 402 is closed at both ends of the well by inner surface 406 of ring 401. Also, it will be appreciated that separator device 400 may be provided with more than one collection chamber.

25 FIG. 6 shows separator device 400 in place within specimen collection cup 410. It can be seen from FIG. 6 that the height of ring 401 is restricted so neither it nor collection

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chamber 402 extend above the level of the open mouth 411 of cup 410 (to avoid interfering with closure of cup 410 by its cap [not shown]). Assay sample fluid 412 remains below separator device 400 in cup 410.

Separator device 400 may be constructed of any sterilizable material which is acceptable
5 for use with fluid assay samples, the identity of which will be known to those of ordinary
skill in the art (e.g., plastics such as polycarbonate and glass). Preferably, the material
will be non-porous and hydrophobic.

E. Methods for Use of the Assay Devices

The method of the invention may be used to detect any analyte present in fluid sample.
10 The invention is especially useful for detection of monoepitopic and polyepitopic
antigens and antibodies associated with pathologies, as well as physiological compounds
and drugs.

The assay devices of the invention are particularly well suited for use in drug screening
assays and for diagnostic testing of organisms. In the former respect, a five drug panel
15 of assay tests is recommended by the National Institute on Drug Abuse (NIDA), which
includes tests for tetrahydrocannabinol and other marijuana metabolites, cocaine
metabolites, opiate metabolites, phencyclidine (PCP, Angel Dust), and amphetamines.
For a more extensive substance abuse testing panel, the choice of analytes tested can
include marijuana metabolites; tetrahydrocannabinol and other marijuana metabolites,
20 cocaine metabolites, opiate metabolites, phencyclidine (PCP, Angel Dust),
amphetamines, barbiturates, benzodiazepines, methaqualone, and propoxyphene. The
analyte test strips for drug tests preferably have the sensitivity equal to the cutoffs
recommended by Substance Abuse Mental Health Service Administration (SAMSHA)
and NIDA, which most employers use. Binders and reagents for use in constructing test
25 strips for use in detecting drugs of abuse are well-known in the art and will not be

described in detail here; however, representative sources of such materials are described in the Examples below.

Subjects undergoing drug tests are often creative in their attempts to adulterate the analyte samples to evade detection of drugs of abuse likely to be present in the sample.

- 5 To minimize the effects of such evasion efforts on results obtainable with the assay devices of the invention, test strips may be provided in the devices which indicate the integrity and condition of the analyte sample. For example, test strips may be provided to simultaneously assay the analyte sample for pH, osmolality (the total concentration of solutes in urine, expressed as mOsm/kg and measured as a function of fluid specific
- 10 gravity), or the presence of albumin.

In test strips for pH, the strip is impregnated with various dyes that respond with different color changes to a pH in the range of 5 to 9. Depending on the acid-base status, urinary pH may range from as low as 4.5 to as high as 8.0. Although this test is done routinely, it neither identifies nor excludes patients with urinary system disease. The test can, 15 however, indicate that the condition of the urine sample has deteriorated.

To test the specific gravity (which is directly proportional to urine osmolality) of an analyte test fluid, analyte test strips are available that measure specific gravity in approximations. For example, U.S. Patent 4,318,709, to Falb *et al.*, issued March 9, 1982, provides a test means for determining the ionic strength or specific gravity of an 20 aqueous test sample, the test means comprising a weakly acidic or weakly basic polyelectrolyte which is at least partially neutralized, and an indicator means capable of producing a detectable response to ion exchange between the polyelectrolyte and the sample. The test device is a carrier matrix incorporated with the test means, and the method for its use involves contacting an aqueous test sample with the device and 25 observing a detectable response. The disclosure of the '709 Patent is incorporated for reference herein.

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Normal urine osmolality varies between 50 and 1200 mOsm/kg (specific gravity between 1.002 and 1.035). Any urine having a specific gravity over 1.035 is either contaminated, contains very high levels of glucose, or the patient may have recently received high density radiopaque dyes intravenously for radiographic studies or low molecular weight

5 dextran solutions.

Commercially available analyte test strips also permit simple and rapid testing for protein. Methods based on dye binding techniques have proven especially useful because dye binding methods are readily automated and provide reproducible and accurate results. In general, dye binding techniques use pH indicator dyes that are capable of

10 interacting with a protein, such as albumin, and that are capable of changing color upon interaction with a protein absent any change in pH. When a pH indicator dye interacts with, or binds to, a protein, the apparent pKa (acid dissociation constant) of the indicator dye is altered and the dye undergoes a color transition, producing the so-called "protein-error" phenomenon. In methods utilizing the dye binding technique, an appropriate buffer

15 maintains the pH indicator even at a constant pH to prevent a color transition of the pH indicator dye due to a substantial shift in pH. Due to the "protein-error" phenomena, upon interaction with the protein, the pH indicator dyes undergoes a color transition that is identical to the color change arising because of a change in the pH. Examples of pH indicator dyes used in the dry phase assay of proteins that are capable of interacting with

20 or binding to proteins and exhibiting "protein-error" color transitions include tetrabromophenol blue and tetrachlorophenol-3,4,5,6-tetrabromosulfophthalein. Simple, accurate and inexpensive protein detection assays have been developed for the detection or measurement of protein in urine and serum (See, e.g., U.S. Patent 5,096,833 to Lau *et al.*, incorporated herein for reference).

25 The method of the invention is performed by applying analyte sample to test strips by immersion (dipstick forms of the device) or by applying the sample dropwise through slot 221 in cap 220 (FIG. 3; representing cassette forms of the device). After waiting a predetermined time, such as from about 15 seconds to about 60 seconds, test results are

viewed through window 111 or 211 (FIGS. 1 and 2), either visually or by an instrument. A color change in test zone 112 or 212 (FIGS. 1 and 2) indicates the presence or concentration of analyte in the sample. When no band appears in test zones, or if the control band is neither distinct nor fully formed, the assay is regarded as incompetent to 5 indicate the presence or absence of analyte in the test samples and may be performed again. In addition, the assay can be made quantitative by employing spectrophotometric or colorimetric techniques, as opposed to visual techniques, in order to more reliably and more accurately measure the degree of color transition, and therefore more accurately measure the concentration of analyte in the test sample.

10 F. Kits

The invention provides a kit useful for the detection of analytes of interest, having a carrier compartmentalized to receive one or more containers holding the multianalyte assay device of the invention or parts thereof. Preferably, the multianalyte assay device is part of a kit which may be composed of the device, instructions for its use, a sample 15 collection cup, a capillary device for measuring test sample, a pipette for introduction of sample to the device, and a desiccant packet.

Desiccant provides low humidity conditions necessary for preservation of reagents during the shelf life of the device. Alternatively, a desiccant tablet or a desiccant packet may be included in an air-tight protective pouch with the device. Instructions for use of 20 the multianalyte assay device may be printed onto the cover or onto the packaging of the multianalyte assay device or may be printed in literature to be packaged with the multianalyte assay device. The kit may additionally include an attached temperature strip, lids for the specimen cup, and the literature. Components of such a kit for use in performing an assay procedure (e.g., excluding printed instructions) are preferably to be 25 sealed in one or more air-tight packages, such as foil packets.

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The following examples are provided to illustrate a use for the invention and do not limit its scope. Unless otherwise noted, all terms and abbreviations used in the examples are standard in the art.

Example 1

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Assay for Six Drugs of Abuse

Six chromatographic strips for detecting drugs of abuse (methamphetamine, opiates/morphine, marijuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgone, benzodiazepine) each of a size of 5 mm x 73 mm were placed in slots of the device of the invention as shown in FIG. 1. Each strip consisted of a 10 colloidal gold-labeled antibody (specific to the target drug) incorporated into the upstream end of the strip (tracer zone) in the middle of a 30 mm fiberglass matrix, and an antigen-BSA binder immobilized in the center (binder zone) of a 22 mm nitrocellulose membrane lying downstream of, and in fluid communication with, the fiberglass matrix (wherein the antigen is either the drug of interest or an analog thereof having the same 15 immunogenicity). Downstream to the nitrocellulose membrane was a 26 mm long filter paper. The matrix, membrane and filter paper were attached on a vinyl sheet so each was in fluid communication, by overlapping 2mm of each of their ends.

15 drops (0.7 ml each) of analyte sample (human urine) were applied to the sample port. Results were read after 10 minutes. The presence or absence of a pink-rose color band 20 in the binder zone indicated negative or positive results for the presence of each drug of interest in the analyte sample.

For comparison, additional aliquots of the analyte samples were separately tested for the presence of the same drugs of abuse by a commercial assay (Syva EMIT EIA II). The second panel of test results correlated with the results obtained according to the 25 invention.

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Although the invention has been described with reference to the presently preferred embodiment, it should be understood that various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.